

## **BIONICAL EMAS GROUP**

### **ANTI-SLAVERY AND HUMAN TRAFFICKING STATEMENT 2022**

**This statement is made by the Bionical Emas Group in compliance with Section 54 of the United Kingdom’s Modern Slavery Act 2015.**

#### **INTRODUCTION**

Modern slavery is the illegal exploitation of people, depriving them of their liberty for personal or commercial gain. It covers a wide range of abuse, exploitation, and coercion, including human trafficking, sexual exploitation, domestic servitude, forced labour, criminal exploitation, and organ harvesting. It is a criminal offence and can affect women, men, and children.

Accordingly, the Bionical Emas Group (referred to in this Statement as “**Bionical Emas**” or “**the Group**”) has a zero-tolerance approach to slavery and human trafficking and is committed to acting ethically and with integrity not only within its Group but in all of its business dealings and relationships. Bionical Emas is committed to effecting, enforcing and continuously improving its measures to detect and eradicate such practices, should they touch upon the Group in any way, particularly in its supply chains. The Group is also committed to ensuring there is transparency in its own business and in its approach to tackling modern slavery throughout its supply chains, consistent with its disclosure obligations under the United Kingdom’s Modern Slavery Act 2015. The Group expects the same high standards from its contractors, suppliers and other business partners and as part of its contracting processes it obliges such third parties to maintain the same standards.

In order to ensure that this commitment is fully realised, the Group has considered in depth the risks associated with its activities and identified and effected measures to mitigate such risks. Further details on this process and the measures identified and effected are set out in this Statement and in the Group’s Anti-Slavery and Human Trafficking Policy, Policy number POL-CORP-10v2.

#### **BIONICAL EMAS GROUP STRUCTURE AND BUSINESSES**

Bionical Emas is a Contract Research Organisation (CRO). Uniquely, the Group offers the following types of services to its pharmaceutical and biotech company clients across the globe:

- **Clinical Development** – The Group’s Clinical Development Division provides services to pharmaceutical and biotech clients who wish to run clinical studies/trials. Bionical Emas’ highly-skilled and experienced Clinical Development teams provide a fully comprehensive service, managing clinical trials at all stages throughout their cycles.

- **Early Access Programs (EAP)** – The EAP division develops and manages programs that facilitate access to investigational drugs (not yet licensed in the applicable territory) outside of the clinical trial space for patients with life-threatening diseases that have exhausted all licensed drugs in their territory. The division provides this highly regulated service to many pharmaceutical companies across many territories, working with healthcare professionals to ascertain patient eligibility for such programs and arranging the supply of the investigational products directly from the client to the treatment centre.
- **Clinical Trials Supply (CTS)** - This division provides services to pharmaceutical and biotech companies who require pharmaceutical products for use (usually as comparator products) within a clinical trial. It involves sourcing such products from the Group's approved global network of suppliers and supplying them to the clients.

The Group also provides other services relating to pharmaceutical product development, such as pharmacovigilance and real world data services, as well as consulting and regulatory services. Accordingly, the Group plays a vital part in bringing innovative, life-changing medicines to patients around the world, pioneering the way treatments are developed and accessed by patients.

The legal structure of the Group is as follows. **Bionical Limited**, a UK-registered limited company, is the parent company of several companies (forming the Bionical Emas Group), the primary trading companies being the following:

- **Bionical Limited**, based in Derbyshire, UK;
- **Emas Pharma Limited** (a UK-registered company based in Letchworth, UK)
- the Group's US company, **Bionical Emas, Inc.**, based in New Jersey; and
- the Group's EU company, **Bionical Emas Limited** (an Irish company, based in Ireland).

The above companies, which all use the trading name Bionical Emas, are fully licensed by the appropriate regulatory authorities for the activities they perform.

This Statement is made on behalf of all of the entities in the Group.

#### **DUE DILIGENCE PROCESSES FOR SLAVERY AND HUMAN TRAFFICKING**

In order to identify and mitigate the risks of slavery and human trafficking occurring *anywhere* within the Group or its supply chain, Bionical Emas adopts the following due diligence processes:

- Regular reviewing of its Slavery and Human Trafficking Policy, taking into consideration whether any improvements to the Policy should be made.
- Ensuring all Group personnel are aware of, and trained on, the above policy.
- Identifying and assessing potential risk areas, including in its supply chains.

- Putting in place measures to mitigate the risk of slavery and human trafficking occurring in the Group or its supply chains.
- Monitoring the effectiveness of its measures, and potential risk areas (particularly in supply chains).
- Encouraging Group personnel to report any issues and protecting whistle blowers.

## RISK ASSESSMENTS AND MANAGEMENT

Identifying the *risk* of modern slavery/human trafficking and *actual* slavery/human trafficking, when it occurs, is not always easy. The Group takes a systematic approach to assessing modern slavery/human trafficking risks, considering two primary types of risk factor as follows: general risk factors; and specific risk factors associated with its own business.

### General risk factors

General risk factors for slavery/human trafficking include the following (as described in the Walk Free Slavery Index\*), some of which risk factors clearly overlap:

- Living within a highly oppressive regime
- Living within a conflict zone (where laws/protections tend to break down)
- Living in extreme poverty
- Living within a country which has no protections/laws in place to prohibit slavery.
- The risk for women and girls is much higher than for men and boys.
- There is a much higher risk for boys and adolescents than for men.
- The risk for children generally is especially high.
- There is a much higher risk for migrants/displaced persons.
- Certain countries have a higher risk than others. For example, the 2018 Slavery Index states that the following 10 countries have the highest risk of slavery: North Korea, Eritrea, Burundi, Central African Republic, Afghanistan, Mauritania, South Sudan, Pakistan, Cambodia and Iran.
- Low-skilled work is also of a higher risk than highly skilled, technical work.
- Seasonal/temporary work is of a higher risk than long-term/permanent work.
- Hazardous/undesirable work is of a higher risk than other work.
- Lengthy, non-transparent supply chains can be a risk factor.

\*Minderoo Foundation's Walk Free initiative is an independent, privately funded international philanthropic human rights organisation based in Perth, Western Australia. Walk Free works towards ending modern slavery in all its forms by taking a strong, multifaceted, and global approach. It produces the Slavery Index on a periodic basis.

### Specific risk factors

Although the Group's risk in relation to *most* of the general risk factors set out above has been assessed by it as low, the Group has identified two risk factors pertaining to its specific activities which may increase the risk level of *some* of the general risk factors:

- The Group operates globally, including in countries where the risk of slavery may be higher. It also employs staff in many different countries.
- The Group transports medicines internationally, via sometimes (but by no means always), lengthy supply chains. These supply chains include third parties offering the following types of services/supplies of goods:
  - Pharmaceutical product manufacturers (globally), for supply of medicinal product
  - Pharmaceutical product wholesalers/distributors (globally), for supply of medicinal product.
  - Logistics providers (globally), transporting medicines
  - Warehouse facilities (globally), storing medicines when required
  - Suppliers of specialised packaging (globally) for transport of pharmaceutical products

The Group has assessed and implemented measures to combat these two specific risk factors, viewed in the light of the general risk factors, as set out in the following sections of this Statement.

### GLOBAL OPERATION RISKS

Bionical Emas has offices/warehouses in the UK, the US and Ireland. The Group also employs staff or engages consultants in a number of further countries. The following safeguards are in place in respect of employment of staff or engagement of consultants, wherever they may be across the globe.

### Employment/Engagement

- The Group's central People Department (based in the UK) adheres to its rigorous recruitment and engagement processes, wherever hires may be located, to ensure fairness and transparency in the recruitment process.
- The Group's People Department ensures that the Group's Equal Opportunities Policy is adhered to at all times, no matter where a worker lives or works.
- Where recruitment agencies are used, their processes are checked before they are used.
- The People Department takes legal/employment advice from country-specific sources where appropriate.
- Personnel /candidate passports or other appropriate forms of personal identity are checked.
- Those not eligible to work in the applicable country are not employed/engaged.
- Children are not employed. We may occasionally employ young adults (i.e., over the age of 16) but only in appropriate roles, with appropriate supervision and pay. We may also occasionally accept young people on short, supervised work experience placements.
- Employment contracts and benefits are, to the extent reasonably possible, kept uniform, regardless of country of employment/engagement.

- It is very rarely necessary (if at all) to employ or engage staff living in conflict zones, repressive regimes or any of the listed high-risk countries.

With these measures in place, and the fact that the roles offered by Bionical Emas tend to be highly skilled/technical, the chances of Bionical Emas personnel being subjected to slavery or trafficking is considered low. However, the Group remains vigilant.

### Clients/third parties

Clients and other third parties with whom the Group interacts may be situated all over the world. Any clients or third parties located in repressive regimes, conflict zones, or one of the listed high-risk countries will be risk-assessed before any commitment is made to work with in such locations or with such clients/third parties. The Group's clients tend to be large or medium-sized, well-funded and sophisticated pharmaceutical companies working in high-tech, highly regulated environments, employing highly-skilled staff. Accordingly, the risk of encountering slavery within such third parties' organisations have been assessed by the Group as low.

### THE GROUP'S SUPPLY CHAINS

Bionical Emas' operations touch on many countries. The *type* of business the Group operates and the *global* nature of its business make it inevitable that the Group will engage with suppliers and supply chains right across the world. The UK's Modern Slavery Act 2015 is particularly focused on supply chains, and UK businesses putting in place effective measures to ensure that they do not unwittingly tolerate slavery in their supply chains.

The Group has carefully assessed the risks relating to its supply chains. Wherever the Group operates, it operates in a highly-regulated, highly-scrutinised environment. The manufacture and distribution of pharmaceutical products is extremely carefully controlled, for obvious reasons, in all countries in which the Group operates. Accordingly, the sector is tightly supervised by many regulatory authorities in many countries. Just as in the UK, EU and US, other countries' regulatory authorities generally require businesses operating in the pharmaceutical sphere to be licenced, demonstrating their compliance with very high ethical and quality standards. This includes not only manufacturers of pharmaceuticals, but also distributors, wholesalers and others operating in the market. By its nature, there *must* be transparency in the supply chain, to ensure that the quality and pedigree of the medicines sourced remains optimum.

The Group's companies hold all necessary licences to perform their services and are subject to regular regulatory agency and client audits/inspections. The Group has in place robust Quality Management Systems and experienced, competent Quality Assurance teams, ensuring the Group's companies meet all required standards, no matter how exacting. For this reason, compliance with regulatory and legal requirements comes naturally to Bionical Emas and is of paramount importance to its people and its business.

Two of the Group's divisions' activities involve the shipping of highly valuable and highly regulated products around the world. Accordingly, the Group relies on its extensive, international network of approved suppliers. This reliance *could* generate a high risk of modern slavery or human trafficking somewhere along our supply chains. However, in our specific sector, this risk is significantly decreased due to the stringent requirements and high levels of scrutiny and transparency governing every aspect of, and link in, the supply chain. Even so, Bionical Emas is not complacent and remains vigilant in attempting to identify and eradicate any such problems from our supply chain. How we do achieve this is set out in the section below.

#### **SUPPLIER ADHERENCE TO THE GROUP'S VALUES AND ETHICS**

To ensure that all those in our supply chain comply with our values and ethics we have in place a rigorous supply chain assessment and compliance program. This is led by staff from the following departments: Legal; Quality Assurance; and the People department. This supplier assessment and compliance program includes:

- Robust assessment of applicable new suppliers, prior to doing business with them, including requirement to complete approval forms and quality/compliance questionnaire.
- Remote or (where applicable) in-person auditing of vendors/suppliers.
- Checking of suppliers' credentials, such as licences held.
- Contractual obligation to comply with all applicable law, including that relating to anti-slavery and human trafficking (with right to terminate if such obligation is breached).
- Contractual right to audit suppliers periodically for the duration of the relationship.
- Contractual obligation on suppliers, to ensure that they hold their own sub-contractors to the same standards.
- Where applicable, effecting of quality/technical agreements setting out clear responsibilities and standards.

#### **THE GROUP'S POLICIES ON SLAVERY AND HUMAN TRAFFICKING**

The Group has in place a robust Anti-Slavery and Human Trafficking Policy, POL-CORP-10v2, which policy sits on the Group's global compliance overlayer, within the Group's Quality Management System. This policy:

- reflects the Group's commitment to anti-slavery and human trafficking in every company within the Group, and to ensuring that there is no slavery or human trafficking in any part of the Group's business or in its supply chains;
- reflects the Group's commitment to acting ethically and with integrity in all of its business relations;
- sets out the risk identification steps and mitigating measures that are taken by the Group to mitigate those risks; and
- ensures Group personnel understand their role in combatting slavery and human trafficking, encouraging escalation of any activities that they suspect could be slavery or human

trafficking, and if needed personnel understanding their ability to ‘whistle blow’ on such matters.

The Training section below sets out how staff are trained on this and other policies.

Several other Group policies are in place which support ethical trading, and support the Group in its commitment to anti-slavery and human trafficking, including:

Anti-Bullying and Harassment Policy	Policy number: COR-POL-000005
Anti-Bribery and Corruption Policy	Policy number: COR-POL-000054
Corporate Social Responsibility Policy (including Ethical Trading and Environment)	Policy number: COR-POL-000032
Equal Opportunities Policy	Policy number: COR-POL-000002
Health and Safety Policy	Policy number: COR-POL-000052
Whistleblowing Policy	Policy number: COR-POL-000010

## TRAINING

To ensure a high level of understanding of the risks of modern slavery and human trafficking in our supply chains and our business, we provide training to our staff. Training may be in person or via our Group-wide electronic learning system, which allows full tracking of compliance with training requirements and creates full records of training. We train our staff on our processes and policies, but also on ‘red flags’ which may indicate slavery is present in particular circumstances, to help our staff identify slavery if they encounter it.

## THE GROUP’S EFFECTIVENESS IN COMBATING SLAVERY AND HUMAN TRAFFICKING

Bionical Emas uses the following key performance indicators (KPI’s) to measure how effective it is in ensuring that slavery and human trafficking is not taking place in any part of its business or supply chains:

- 1 Number of slavery or human trafficking events (or suspected events) identified during each financial year (within our own business or businesses within our supply chains).

**To date, no such incidences have been identified.**

- 2 Number of slavery or human trafficking concerns that have been raised to the Group either within Bionical Emas or relating to its supply chains during each financial year.

**To date, no such reports have been made.**

## FURTHER STEPS

Following a review of the effectiveness of the steps we took in 2022 to ensure that there is no slavery or human trafficking in our supply chains, we intend to take the following further steps to combat slavery and human trafficking:

- 1 To continue to review our Anti-Slavery and Human Trafficking Policy annually, rather than bi-annually, prior to the drafting and publication of the annual Statement.
- 2 To strengthen our vendor/supplier assessment and audit procedure further by engaging a new vendor management role within the company to ensure a robust onboarding and management of suppliers/third parties.

This statement is made pursuant to section 54 of the UK's Modern Slavery Act 2015 and constitutes the Group's slavery and human trafficking statement for the financial year ending 31 December 2022. It is approved by the directors of the Bionical Emas Board and signed by its CEO below.

DocuSigned by:

*Tom Watson*



Signer Name: Tom Watson

Signing Reason: I approve this document

Signing Time: 14-Aug-2023 | 04:03 PDT

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**Tom Watson**

**Director of Bionical Limited**

**CEO of the Bionical Emas Group**